



NDA 11-483/S-015

Wyeth Ayerst Laboratories
Attention: Nanette E. Holston
Associate Director, Global Brand Management
P.O. Box 8299
Philadelphia, PA 19101-8266

Dear Ms. Holton:

Please refer to your supplemental new drug application dated August 24, 2000, received August 28, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Synalgos DC (dihydrocodeine bitartrate) Capsules.

We acknowledge receipt of your submission dated October 23, 2000.

This supplemental new drug application provides for the addition of a *Geriatric Use* subsection to the **PRECAUTIONS** Section of the label.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text and with the minor editorial revisions listed below. Accordingly, the supplemental application is approved effective on the date of this letter.

Please revise the titles of the label sections in accordance with 21 CFR 201.56(d)(1) as follows:

<u>Proposed</u>	<u>21 CFR 201.56(d)(1)</u>
Actions	Clinical Pharmacology
Indications	Indications and Usage
Drug Interactions	should precede "Geriatric Use" in Precautions section

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted draft labeling (draft package insert submitted August 24, 2000). These revisions are terms of the approval of this application.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 11-483/S-015." Approval of this submission by FDA is not required before the labeling is used.

Food and Drug Administration
Rockville MD 20857

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Carmen DeBellas, Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Jonca Bull, M.D.
Acting Director
Division of Anti-Inflammatory, Analgesic and Ophthalmic
Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Jonca Bull

10/31/01 10:19:34 AM